

DOCKET NO.: WARF-0135 (P00154US)  
Application No.: 09/651,290  
Office Action Dated: July 12, 2002

PATENT  
REPLY FILED UNDER EXPEDITED  
PROCEDURE PURSUANT TO 37 CFR § 1.116

**REMARKS/ARGUMENTS**

This application is under final rejection. A Notice of Appeal was filed on January 16, 2003. A Request for Continued Examination, accompanied by an Amendment and Request for Reconsideration, is submitted herewith in lieu of an appeal brief.

The July 12, 2002 Official Action and references cited therein have been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

**Status of the claims:**

Claims 1-12, 14, 16-27 and 29 are currently pending. In the July 12, 2002 Official Action, the following rejections were withdrawn:

- a) rejection of claims 14 and 15 under 35 U.S.C. §112, second paragraph;
- b) rejection of claims 1-12 and 16-27 under 35 U.S.C §102(b); and f
- c) rejection of claims 14, 15, 29 and 30 under 35 U.S.C. §102(e).

Applicant notes that, in items b) and c) above, the examiner listed claims 15-24, 31-32 and 41, and claims 57-59, respectively, rather than the claims that actually had been rejected in the previous action. It is believed that this was merely a typographical error; hence, Applicant is proceeding under the assumption that the prior art rejections issued in paragraphs 4 and 5 of the first Official Action have been withdrawn in their entireties.

In the July 12, 2002 Action, claims 1-12, 14, 16, 17 and 29 were finally rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement by the specification. Claims 18-27 were objected to for depending upon rejected base claims. Though not stated by the examiner, claims 18-27 therefore should be allowable if rewritten in independent form, since those claims do not stand rejected on any ground.

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**Amendments in this paper:**

In accordance with the present amendment, claims 14 and 28 are canceled without prejudice. It should be noted that claim 28 should have been canceled in response to the Restriction Requirement, but claim 29 was erroneously canceled instead. Accordingly, claim 28 is now canceled. Applicant intends that claim 29 should remain canceled as well.

Also in accordance with the present amendment, the claims have been amended to now call for a recombinant bacterium instead of an antibacterial agent. This amendment is made to clarify that the utility of the recombinant bacteria of the present invention goes beyond their use for treatment of human subjects and encompasses their utility in other areas, including but not limited to food and agronomic utility. Claims 1 and 16 have also been amended to remove the term "optionally" prior to reference to screenable markers.

Applicant asserts that the presently amended claims satisfy all requirements for enablement under 35 U.S.C. §112, first paragraph, and that the claims as amended are in condition for allowance.

**Rejection under 35 U.S.C. §112, first paragraph:**

The examiner has rejected claims 1-17 for lack of enablement, asserting that the specification does not enable practice of the invention recited by those claims without undue experimentation. The examiner states that the specification does not provide evidence that the claimed antibacterial agent can maintain stability or that pharmaceutical preparations comprising the agent are capable of treating bacterial infections. Applicant asserts that the claims as amended are drawn to recombinant bacteria with utilities other than in pharmaceutical preparations for use in treatment of humans, and further that stability of the plasmid in either the donor or the recipient is not critical to the operation of the invention as

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claimed. In the case of the donor cells, the more important parameter is that the bacteria are capable of conjugatively transferring the plasmid to a recipient cell. Such cells can be prepared immediately prior to performing the conjugation, wherein there would be substantially little opportunity for plasmid loss from the donor cells. As to the recipient cells, it is expected that the recipient cells would be substantially prevented from further multiplying, due to the effects of the runaway plasmid or the killer gene transferred to the recipient during the conjugation.

The specification clearly teaches how to make the recombinant bacteria claimed in claims 1-17. The specification teaches recombinant bacteria containing 'killer plasmids', (e.g. plasmids which undergo runaway replication, or which contain 'killer genes') that are conjugatively transferred from a nonpathogenic donor to a pathogenic recipient. The specification teaches that both *ori* and *tra* sequences are required. The specification further points to several *ori* and *tra* sequences suitable for use in the plasmids of the invention, and teaches how to assemble the appropriate plasmid constructs. The specification teaches that conjugation requires contact between the cells and that the transfer of genetic traits can be mediated by many plasmids, and teaches several examples from a number of different bacteria. Furthermore, the specification teaches that conjugation is among the most efficient natural genetic transfer mechanisms.

The examiner goes on to assert that the invention as claimed is not enabled because of an alleged deficiency in describing how to use the claimed invention. However, Applicant is not claiming methods of use, but instead is claiming a novel composition of matter that has several specific, substantial and credible utilities that are recited in the specification. An enabling description of how to make the claimed compositions, combined with a recitation of

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at least one specific, substantial and credible utility for the claimed compositions, should be more than sufficient to satisfy the requirements of 35 U.S.C. §112, first paragraph.

Furthermore, Applicant notes that claims 18-27 have not been subjected to the same rejection for lack of enablement as have claims 1-17, yet the subject matter of those claims is taught in the same manner as the subject matter of claims 1-17. Accordingly, it follows that practice of the invention of claims 1-17 is enabled by the specification, in view of the fact that the examiner has deemed practice of the invention of claims 18-27 to be so enabled.

**Conclusion:**

In view of the amendments submitted herewith and the foregoing remarks, the presently pending claims are believed to be in condition for allowance. Applicant respectfully requests early and favorable reconsideration and withdrawal of the objections and rejections set forth in the July 12, 2002 Official Action, and allowance of this application.

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